510(k) SUMMARY K090425

Guided Lateral Interbody Fusion (GLIF) System
510(k) SUMMARY
February 2009

MAY 19 2009

Company: Alphatec Spine, Inc.
5818 El Camino Real
Carlsbad, CA 92008 USA
Direct: (760) 494-6771
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Contact Person: Mary Stanners, Regulatory Affairs Specialist II

Trade/Proprietary Name: Guided Lateral Interbody Fusion (GLIF) System

Common Name: Intervertebral Body Fusion Device
Vertebral Body Replacement Device

Classification Name: Intervertebral Body Fusion Device
Spinal Intervertebral Body Fixation Orthosis

Classification Number(s)/Product Code(s): 21 CFR 888.3080 (MAX)
21 CFR 888.3060 (MQP)

Product Description:

The Guided Lateral Interbody Fusion (GLIF) System will be comprised of interbody implants, curved access instruments and specialized disc preparatory instruments. The Guided Lateral Interbody Fusion (GLIF) System provides a lateral approach to the spine from a posterior angle while the patient is in the prone position. The lateral access technique allows a larger cage to be implanted similar to an anterior lumbar interbody fusion sized cage and patient is already in the prone position which eliminates the need to break the sterility field and flip the patient for supplemental fixation.

Indications for Use:

When used as an intervertebral body fusion device, the Guided Lateral Interbody Fusion (GLIF) System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have had six months of non-operative treatment. The GLIF System is to be used with a supplemental fixation system and autogenous bone graft.

When used as a vertebral body replacement device, the Guided Lateral Interbody Fusion (GLIF) system is intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or

unstable vertebral body due to tumor or trauma (i.e. fracture). The GLIF System is intended for use with supplemental spinal fixation system. Specifically the GLIF System is to be used with Alphatec Zodiac Polyaxial Spinal Fixation System or the Alphatec Mirage Top Tightening Spinal System. Furthermore the GLIF System is intended for use with allograft.

Substantial Equivalence:

Data was provided which demonstrated the Guided Lateral Interbody Fusion (GLIF) System to be substantially equivalent to the Novel Spinal Spacer System (K080699) and the Nuvasive CoRoent (K071795). The substantial equivalence is based upon equivalence in indications for use, design, material and function.

Performance Data:

The test results demonstrate that the mechanical performance of the GLIF System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Alphatec Spine, Inc.
% Ms. Mary Stanners
Regulatory Affairs Specialist II
5818 El Camino Real
Carlsbad, California 92008

Re: K090425
Trade/Device Name: Guided Lateral Interbody Fusion (GLIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: February 17, 2009
Received: February 19, 2009

Dear Ms. Stanners:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): TBD

Device Name: Guided Lateral Interbody Fusion (GLIF) System

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Prescription Use __X__ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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